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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Multiple Energy Technologies, LLC

Plaintiff,

v.

Hologenix, LLC,

Defendants.

Hologenix, LLC

Counterclaimant,

v.

Multiple Energy Technologies, LLC

Counter-Defendant.

Case No. 2:19-cv-01483-PA-RAO

HOLOGENIX'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

[Filed Concurrently With (1) Declaration of Seth Casden, (2) Declaration of Michael Billing, (3) Declaration of Noel S. Cohen, and (4) Evidentiary Objections.]

Date: June 3, 2019
Time: 1:30 p.m.
Before: Hon. Percy Anderson

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiff/Counter-Defendant Multiple Energy Technologies, LLC ("MET") seeks an overbroad, mandatory injunction under the Lanham Act in an attempt to cripple its competitor Defendant/Counter-Claimant Hologenix, LLC ("Hologenix"). MET and Hologenix both produce and sell a bioceramic material to manufacturers that can be embedded in textiles. The bioceramic material captures body heat and converts it to Far Infrared ("IR") energy that reflects back on the body. Both companies make certain claims about their products, including that they can promote local blood flow. The difference between MET and Hologenix is that Hologenix spent nearly a decade working with FDA, including undertaking several clinical studies, which led FDA to issue a 513(g) determination to Hologenix.

MET admittedly knew nothing about Hologenix's FDA interaction, yet seeks an extremely broad, mandatory injunction on the basis that the FDA had made no determinations regarding Celliant. The basis for this extraordinary relief is MET's speculative assumption that tweets, social media posts and third-party articles regarding Hologenix's product, Celliant, caused the demise of MET's business. MET's failure is not the fault of Hologenix and this Court should not take the extreme step of issuing a sweeping, overbroad injunction forcing Hologenix to issue corrective advertising based on the speculation of MET and its experts.

During its lifetime MET apparently was only able to land two customers, Under Armour ("UA") and American Textiles, Inc. ("ATC"). With respect to UA, Hologenix was in discussions with UA for nine years before entering into a contract in 2018. At the behest of UA, Hologenix also began working with ATC in 2018. MET has submitted no admissible evidence that Hologenix's alleged false advertising caused UA or ATC to do business with Hologenix rather than MET. Rather than look in the mirror, MET has filed this frivolous lawsuit and now asks the Court to order a mandatory and extremely broad injunction. It should not do so

because MET has failed to satisfy its heavy burden to obtain this requested provisional relief for a number of reasons.

First, there is no likelihood of immediate and irreparable injury absent injunctive relief. The conduct MET seeks to enjoin began in July 2017. [Complaint, Doc. 1, at ¶¶ ¶¶ 3, 20-34, 37, 38, 42-51, 83.]. The only concrete allegations of harm are that UA and ATC terminated their agreements with MET in July 2017 and July 2018, respectively. [*Id*. at ¶¶ 97-99, 115.] MET alleges that the terminations were because of allegedly false statements that Hologenix publicly made about its product. Yet, MET waited until February 28, 2019 to file this lawsuit and then waited an additional two months, until April 22, 2019, to file this Motion. If there were truly irreparable and imminent harm on the horizon, MET should have filed this action in 2017 or 2018. A two-year delay in seeking injunctive relief is anathema to the principles that such relief requires.

In addition, MET's own evidence establishes that it is not likely to suffer imminent and irreparable harm absent injunctive relief, the critical factor in determining whether provisional relief is necessary. Specifically, MET admits that it "no longer has any customers or prospects for customers in this space." That admission is fatal to MET's Motion. Further, even if MET had met its burden, injunctive relief is still not warranted because monetary damages are an adequate remedy. For each cause of action, MET seeks significant monetary damages, including Hologenix's profits, damages to MET, treble damages, punitive damages and attorneys' fees. There is no irreparable harm here and for this reason alone, the Motion should be denied.

Second, MET is not likely to succeed on the merits. MET and Hologenix took very different approaches to FDA. Hologenix spent nearly a decade working with FDA on how Celliant would be regulated. After this decade of interaction, FDA determined that Celliant is a medical device and general wellness product, and specifically advised Hologenix of the appropriate language to inform the public of

this determination. [*See* Declaration of Seth Casden, ¶¶ 11-30]. As such, Hologenix did nothing wrong by publicizing that true statement and should not be enjoined from doing so moving forward.

Third, MET has not and cannot establish that any of the alleged false or misleading statements were material to purchasers of MET or Hologenix's products. Plaintiff complains about a few social media posts and articles linked to Hologenix's website that state that its product is "FDA approved" or "FDA determined." Yet, despite **waiting nearly two years** to file this Motion, MET has not and cannot identify a single third party that even read these posts or articles, let alone decided to purchase Hologenix's product over MET's product because of these posts or articles. If MET's claim that Hologenix engaged in a "massive, nationwide media campaign" were true, it would have been able to point to more than a few errant social media posts and stories by news outlets.

Fourth, MET cannot establish that the allegedly false statements were the proximate cause of any harm to MET. In that regard, the only evidence Plaintiff can muster is a triple hearsay statement from its CEO, Shannon Vissman, that "[i]n a conversation with a MET executive, an American Textile executive said Under Armour switched to Hologenix specifically so that Under Armour could use Hologenix's promotional statements." [Declaration of Shannon Vissman, Doc. 24-1, ¶ 12]. Incredibly, that is the entirety of the supporting factual evidence supporting MET's request for this extraordinary relief. There is no declaration from this mysterious MET executive, there is no supporting declaration from UA or ATC and there is no assertion about when this alleged conversation even took place. In fact, MET has failed to provide even a single declaration from a customer or prospective customer setting forth their reliance on any alleged false or misleading tweets or news articles, let alone evidence that these statements also caused an existing or prospective customer not to conduct business with MET. Since MET cannot link the alleged misleading statements to any harm, or even a

single purchasing decision, MET's claims fail as a matter of law.

Fifth, MET's request for injunctive relief is barred because of the doctrine of unclean hands. MET admits that it makes numerous claims about the efficacy of its own product that are not substantiated by competent and reliable scientific evidence. These are the very claims that MET now asks the Court to enjoin Hologenix from making, even though FDA has actually reviewed Hologenix's clinical studies and determined the claims it makes about Celliant are appropriate.

Finally, MET cannot satisfy the other elements necessary to establish injunctive relief as the balance of the equities does not tip in its favor and an injunction is not in the public interest. For all of the aforementioned reasons, and as detailed below, the Motion should be denied.

II. FACTUAL BACKGROUND

A. Development of Celliant

Hologenix was founded in 2002 to produce and market Celliant, a patented technology comprised of a proprietary mix of naturally-occurring thermo-reactive materials that can be embedded into the core of a yarn or applied to a wide variety of fabrics. [*See* Casden Decl., ¶¶ 3-4, 6-7.] The Celliant mineral matrix captures body heat and converts energy into IR energy, which is emitted back to the body where it can be absorbed by the tissues. [*Id*. ¶ 6, 8-10]. Hologenix performed thousands of tests and analyses to examine the efficacy of its product. [*Id*. ¶ 9.] Since 2003, Hologenix has conducted nine clinical studies on Celliant. [*Id*.] As the technology and its physiological effects became apparent through clinical studies, Hologenix began the process of determining how FDA would regulate Celliant. [*Id*. at ¶ 11.]

B. FDA Interaction

1. FDA Process

The 513(g) process, established under Section 513(g) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), provides a means for device manufacturers,

like Hologenix, to submit a written request to FDA seeking its' views regarding the classification and regulatory requirements applicable to a particular device. [*See* Declaration of Michael Billing ("Billing Dec"), ¶¶ 1-13] In a typical 513(g) situation, FDA does not review safety or efficacy data for the device and FDA's 513(g) response does not constitute a device classification decision or an FDA clearance or approval for marketing. [*Id*. ¶ 14.] Hologenix's interaction with FDA was not a "typical" situation, as MET's FDA expert (who admittedly did not review Hologenix's decade-long correspondence with FDA) wrongly assumes. [*Id*. ¶¶ 19-21.]

Medical devices that were not commercially marketed before May 28, 1976 are automatically classified as Class III devices[1] unless FDA either (a) issues an order classifying the device into Class I or Class II, or (b) determines, in response to a 510(k) submission, that the device is substantially equivalent to an appropriate predicate device. [*Id*. ¶ 17.] In 1997, Congress established a new *de novo* pathway to limit unnecessary expenditure of FDA resources for low-risk (Class I or Class II) devices. [*Id*.] The *de novo* process provides an alternative pathway for low-risk devices to receive classification as Class I or Class II where the 510(k) pathway is unavailable because of the lack of a legally marketed predicate. [*Id*.] A *de novo* request must include clinical or non-clinical data relevant to ensure reasonable assurance of the safety and effectiveness of the device. [*Id*.]

2. Hologenix Interactions with FDA

Hologenix first approached FDA in 2009 to determine the regulatory pathway and status of Celliant products. [Casden Decl., ¶ 12.] Hologenix engaged

[1] FDA has three classifications of medical devices. Medical devices classified by FDA as "Class III" devices must submit a premarket approval ("PMA") application and obtain approval prior to marketing the device. [Billing Decl., ¶ 16.] A PMA is the most stringent type of device marketing application and is based on a determination by FDA that there is sufficient scientific evidence that the device is safe and effective for its intended use. [*Id*.]

repeatedly with FDA over the next two years and in March 2011 Hologenix presented a 513(g) submission to FDA, seeking feedback as to how FDA would classify certain athletic apparel that incorporated the Celliant material, and what regulatory framework the agency would apply to that apparel. [*Id.* ¶ 13.] Subsequently, FDA indicated that Hologenix would need to obtain premarket review of the Celliant-containing products. [*Id.* ¶ 14.]

Because there were no products on the market that could serve as an appropriate predicate to support premarket review through the 510(k) pathway, in October 2011, Hologenix filed a "pre-IDE" submission to FDA seeking additional guidance. [*Id.* ¶¶ 14-15.] Based on the guidance received on its pre-IDE submission, in 2012, Hologenix decided to undertake a clinical study and submit a *de novo* request for Celliant. [*Id.* ¶ 16.] On March 17, 2014, Hologenix filed a *de novo* request for FDA review of Upper Torso Garments which incorporated Celliant, seeking to have the garments reclassified out of Class III and into "No Significant Risk" ("NSR") and Class II. [*Id.* ¶ 17.]

The Hologenix *de novo* request included a substantial body of scientific evidence – including nine Celliant clinical studies and two published physical material papers – demonstrating (a) the effects of IR technology, generally; (b) that Celliant exhibits IR effects; and (c) that IR products, including Celliant products, have desirable and helpful physiological effects on the human body. [*Id.* ¶ 18.] In July 2014, FDA sent Hologenix an eight-page letter with sixteen questions in which it indicated that, following the agency's initial scientific review of the *de novo* request, it had identified certain deficiencies in the application. [*Id.*] The letter sought responses on a variety of issues, including specific questions about clinical study data provided in the *de novo* submission. [*Id.*] In particular, the letter posed several questions specifically related to Hologenix's pivotal Celliant clinical study.[2]

[2] This 2014 clinical study (recently published) found that fabrics containing Celliant increased oxygenation in body tissue. This single-blind, randomized controlled study, involving 153 subjects, examined the impact of wearing a Celliant garment on the upper

[*Id*.] Hologenix responded to FDA's deficiency letter on September 3, 2014, leading to an April 28, 2015 six-page letter from FDA declining Hologenix's *de novo* request for classification of the Celliant garments into NSR and Class II. [*Id*. ¶¶ 19-20.] The letter stated that FDA continued to have questions about the scientific data that Hologenix provided to the agency in support of its *de novo* request. [*Id*. ¶ 20.]

Based on Hologenix's review of FDA's denial letter, Hologenix believed that FDA had an incomplete and incorrect understanding of Celliant and the relevant scientific evidence. [*Id*. ¶ 21.] Hologenix met twice with FDA in June 2015 to address the agency's questions and concerns. [*Id*. ¶ 22.] In advance of each meeting, Hologenix submitted proposed questions to FDA, and FDA responded with preliminary written responses. [*Id*. ¶ 23.] In addition, Hologenix's pre-meeting submission also sought FDA's feedback regarding the acceptable scope and type of claims that would be permitted for Celliant products, which FDA provided. [*Id*. ¶ 24.]

In August 2015, Hologenix engaged Experien Group LLC as medical device consultants to assist Hologenix in its continued interaction with FDA. [*Id*. at ¶ 25.] Ultimately, after continued interaction between Hologenix, Experien Group and FDA to clarify the issues, FDA determined in 2016 that the *de novo* process was not, in fact, required for Celliant products provided they were intended for healthy individuals. [*Id*. ¶ 26.] Instead, in August of 2016, having reviewed the data Hologenix had provided, FDA presented Hologenix with a four-page regulatory

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torso to determine whether significant differences in tcP02 existed between the Celliant garments and control garments. The study found that the Celliant garment consistently yielded higher tcP02 levels, to a statistically significant degree, versus the control garment at 30, 60, and 90-minute intervals, and that the effect increased over time. The typical percentage change between tcP02 levels, when viewed at 30, 60, and 90-minute intervals, ranged from 8.2% to 8.8%. *See* Washington, et al., *Randomized Controlled Trial Comparing the Effects of Far-Infrared Emitting Ceramic Fabric Shirts and Control Polyester Shirts on Transcutaneous PO2*. J. Textile Sci. Eng., 8:349 (2018). This study was referred to as "Study HC1-2" in the correspondence between the FDA and Hologenix leading up to the June 2015 meeting between FDA and Hologenix.

options table that outlined several potential approaches for applications ranging from simple wellness claims through the filing of a new *de novo*. [*Id*.] One option was the submission of a new 513(g) – that would permit Hologenix's proposed claims about local circulation and blood flow while allowing the Celliant products to be classified as medical devices. [*Id*.]

3. FDA Determines That Celliant Products are "Medical Devices" and Permits Use of that Determination in Public Statements.

On October 21, 2016, Hologenix submitted a new 513(g) request to FDA. [*Id*. at ¶ 27.] On June 8, 2017, the FDA issued a **513(g) determination letter determining that Celliant products are medical devices and general wellness products**. [*Id*.] FDA advised Hologenix that it was acceptable to use that phraseology to describe the result of the 513(g) consultation to the public, in addition to certain claims about Celliant, like increased blood flow. [*Id*.] Ultimately, the 513(g) determination letter was the result of nearly a decade of interaction with FDA, and approximately $500,000 in costs associated with the preparation and submission of various requests and other documents to that agency. [*Id*. ¶ 29.] This decade-long interaction involved substantial review by, and discussion with, FDA of the scientific evidence Hologenix developed. [*Id*. ¶ 30.]

In meetings and discussions with FDA throughout that decade-long period, the agency asked a multitude of detailed questions about the science on IR, generally, and Celliant, specifically, and did not simply offer a view on Hologenix's proffered claims based on its historical notions of the line between medical devices and general wellness products. [*Id*.] The interaction between FDA and Hologenix both before and after Experien Group was engaged was unlike a more "typical" 513(g) process because FDA undertakes a far more substantive review of the scientific data during the *de novo* process than it does in response to a 513(g) submission. [Billing Decl., ¶ 21.] The path Hologenix followed with FDA is available to any owner or manufacturer of a product that produces IR, as is FDA's

classification and the language it has advised can be used to describe Hologenix's status. [Casden Decl., ¶ 31.] It is apparent that MET chose not to undertake this effort and now seeks to punish Hologenix for doing so.

C. Hologenix's Interactions with UA and ATC

Throughout the years, Hologenix has sought to promote the Celliant technology to manufacturers of textiles, apparel, bedding and others through a wide variety of industry-specific marketing efforts, including meetings with numerous potential customers globally, appearing and presenting at multiple conferences, and promotion of the product at trade shows. [*Id*. ¶ 33.] In the course of these efforts, Hologenix encounters many competitors, but rarely encounters MET. [*Id*.]

From 2009-2018, Hologenix was in varying stages of discussions with UA with respect to supplying Celliant for UA to use in some of its products. [*Id*. ¶ 34.] These efforts led to Hologenix signing an agreement with UA on February 23, 2018. [*Id*. ¶ 35.] At the request of UA, Hologenix was also in discussions with ATC in 2017 with respect to supplying it with Celliant to use in some of its products and began doing so in 2018. [*Id*. ¶ 36.]

Hologenix never had, and does not now have, a marketing plan that describes the technology as "FDA-approved." [*Id*. ¶ 37.] On fewer than ten occasions out of thousands of social media posts, employees of Hologenix or consultants authorized to post on its behalf erroneously referred to Celliant technology as "FDA-approved." [*Id*. ¶ 38.] It appears that some journalists have also mistakenly described Celliant as "FDA-approved." As MET concedes, Hologenix removed such references to this terminology as soon as it was brought to Hologenix' attention. [*Id*.]; Doc 24 at 9, 12.

III. LEGAL ARGUMENT

A. Legal Standard

"A preliminary injunction is 'an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of

persuasion.'" *Lopez v. Brewer*, 680 F.3d 1068, 1072 (9th Cir. 2012) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972, 117 S.Ct. 1865, (1997) (per curiam)). Plaintiff's seeking a preliminary injunction must establish that (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm **in the absence of preliminary relief**; (3) the balance of equities tips in their favor; and (4) a preliminary injunction is in the public interest. *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 129 S.Ct. 365, 374, (2008) (emphasis added).

B. MET Failed to Establish a Likelihood of Irreparable Harm

"[S]uffering irreparable harm prior to a determination of the merits is '[p]erhaps the single most important prerequisite for the issuance of a preliminary injunction.'" *Nutrition Distribution LLC v. Lecheek Nutrition, Inc.*, 2015 WL 12659907, at *6 (C.D. Cal. 2015) (citing 11A Charles A. Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE § 2948.1 (3d ed. 1998)). "Further, the harm identified may not be speculative and Plaintiffs must show more than the possibility of some remote further injury." *Id*. (citing *Winter*, 555 U.S. at 21-22).

As a result, a plaintiff must present **actual evidence** of irreparable injury. *See Herb Reed Enters., LLC v. Fla. Entm't Mgmt., Inc.*, 736 F.3d 1239, 1251 (9th Cir. 2013) ("Those seeking injunctive relief must proffer evidence sufficient to establish a likelihood of irreparable harm.") "[U]nsupported and conclusory statements regarding harm [plaintiff] **might** suffer" is insufficient to warrant the imposition of a preliminary injunction. *Id*. at 1250 (emphasis added); *see also American Passage Media Corp. v. Cass Commc'ns, Inc.*, 750 F.2d 1470, 1473 (9th Cir. 1985) (same). MET has not offered actual evidence that it will suffer irreparable injury in the absence of a preliminary injunction.

1. MET's Evidence of Irreparable Harm is Insufficient.

MET's factual support for its argument that it will suffer irreparable harm is comprised entirely of unsupported and conclusory statements from its CEO. (Doc. 24 at 26) (citing Vissman Decl. at ¶ 17). In *American Passage*, relied upon by

MET, the Ninth Circuit found that this exact type of evidence – unsupported statements from an executive regarding how a misleading statement resulted in the business nearly shuttering its doors – was insufficient. 750 F.2d at 1474.

Stuhlbarg Int'l Sales Co. v. John D. Brush & Co., another case relied upon by MET, is also not helpful to its Motion. There, the plaintiff offered proof of the irreparable harm it would have endured, including a lost contract with a new customer and immediate harm to its business reputation and goodwill due to its inability to complete an order. 240 F.3d 832, 841 (9th Cir. 2001). That is completely different from the facts here. MET would not be breaching a contract absent an injunction like the plaintiff in *Stuhlbarg*. To the contrary, MET alleges that the purported false advertising at issue here interfered with contracts in 2017 and 2018, not in 2019. [*See* Complaint at ¶¶ 99, 115.] MET admittedly "no longer has any customers or prospects for customers in this space." *See* Motion at 12:1-2. As such, there is no credible evidence that absent a preliminary mandatory injunction, MET is likely to suffer irreparable harm.

2. MET Has Not Offered any Evidence of Future Harm.

MET's sole support for the loss of two of its business contracts consists of vague statements from its CEO, Mr. Vissman, regarding a conversation that an unnamed source at ATC had with an unnamed MET executive regarding UA's decision to enter into a contract with Hologenix – on an undisclosed date. *See* Doc. 24-1 at ¶¶ 10, 12. These anonymous and triple hearsay statements are insufficient to support a finding of irreparable harm. Further, any harm that MET imagines because of Hologenix's discussions with UA and ATC has **already** happened, and there is no allegation of any threat of concrete future harm because of the purported false advertising. Again, MET alleges that it "has no customers and has no current prospect of finding any" [Motion, Doc. 24 at p. 19:14-16]. Although MET argues that is Hologenix's fault, it fails to offer **any** evidence that potential customers read and were actually influenced by the alleged false advertisements.

More fatal to MET's Motion, MET concedes that Hologenix already removed the "FDA-approved" statements upon which it hinges its entire motion. Accordingly, for purposes of the "FDA-approved" statements, the Motion is moot. *Hendrickson v. eBay, Inc.*, 165 F. Supp. 2d 1082, 1095 (C.D. Cal. 2001) (holding that a plaintiff is not entitled to injunctive relief where the advertisements were no longer being used and there was no demonstrated intention of using the advertising in the future); *Lecheek Nutrition*, 2015 WL 12659907, at *7 (need for a preliminary injunction was likely moot where "the conduct as issue has already ceased and subsequent events have made it clear that the allegedly wrongful behavior cannot reasonably be expected to recur.").

Here, the evidence shows that the "FDA-approved" posts were rare mistakes and that Hologenix has no intent to make such statements in the future.[3] Accordingly, these infrequent past statements are not relevant to the instant motion. Regarding the term "FDA determined", Hologenix was explicitly authorized by the FDA to use such language in communications with the public. [Casden Decl., ¶ 27.]

3. MET's Delay in Seeking Injunctive Relief is Indicative of a Lack of Irreparable Harm.

"[A] delay in seeking injunctive relief is probative of a lack of any irreparable harm." *Art Attacks Ink, LLC v. MGA Entm't, Inc.*, 2004 WL 7333800, at *15 (S.D. Cal. 2004); *see also Playboy Enter., Inc. v. Netscape Communications Corp.*, 55 F. Supp. 2d 1070, 1090 (C.D. Cal. 1999) (finding no irreparable injury where plaintiff delayed seeking injunctive relief for eleven months after the alleged infringing conduct occurred). Like the case at bar, in *Art Attacks*, the plaintiff waited twelve months before moving for injunctive relief because the plaintiff was purportedly investigating the nature and scope of the alleged infringement. *Id.* at

[3] Although MET points to a 2019 article written by a third-party journalist that states Celliant was "FDA-approved," Hologenix has already removed references to "FDA-approved" from its website and social media posts. [*See* Casden Decl., ¶ 38.]

*16. The court determined this delay was "unjustified" and "weighs against the finding of irreparable injury." *Id.* The same holds true here: MET alleges that UA terminated its contract with MET in 2017 because of the purported false advertising earlier that year, yet waited over two years to seek injunctive relief.[4]

The cases that MET cites in support of its argument that its delay was justified are inapposite. In *Arc of California v. Douglas*, the plaintiff sought to enjoin a series of cuts to California's funding of home-and-community based services provided to developmentally disabled persons. 757 F.3d 975, 978-979 (9th Cir. 2014). The court found that the delay in seeking injunctive relief was not particularly probative because there were multiple cuts enacted over a period of two years, the most recent being three months before injunctive relief was sought, that created a cumulative effect. *Id.* at 991. Here, the harm that MET alleges – the termination of its contracts with UA and ATI – occurred years, not months, before it sought injunctive relief. Unlike *Arc of California*, there is no evidence of worsening or cumulative harm.

Similarly, *Disney Enterprises, Inc. v. VidAngel, Inc.* is of little help to MET. In *VidAngel*, the defendant began beta-testing of its service in July 2015, in which it bought DVD or Blu-ray discs of copyrighted works of studios, decrypted the discs and uploaded them to a computer for live streaming, after breaking them into segments that could be tagged for categories of inappropriate content. 869 F.3d 848, 853 (9th Cir. 2017). VidAngel then offered the copyrighted works to consumers that could be scrubbed of inappropriate content, sometimes before the copyrighted work was available for other streaming services. *Id.* at 854. The

[4] In an apparent attempt to justify that delay, MET notes that it filed two FOIA requests in July 2018, and then requested expedited treatment in October 2018. *See* Motion at 11:14-18. MET thus proclaims that "with no prospect of obtaining any confirmation from the FDA regarding Hologenix's claims . . .MET proceeded to file this lawsuit." *Id.* at 11:22-23. But MET did not immediately file a lawsuit. Instead, I waited another four and a half months, until February 28, 2019, to do so and then waited almost two more months, until April 22, 2019, to file this Motion.

studios sued VidAngel and sought injunctive relief in June 2016, when VidAngel expanded from beta-testing to a product roll-out. *Id.* at 991. The court held that this delay was reasonable and not a factor against a finding of irreparable harm. *Id*.

Again, MET concedes that Hologenix began making the sued-upon statements in 2017, but claims that it is only now, two years later, that the harm is irreparable. There is no justification for this delay and MET's failure to take action sooner completely undermines its allegations of irreparable harm.

C. The Facts and Law on the Merits Do Not "Clearly Favor" MET

When a party is seeking a mandatory injunction, they "must establish that the law and facts *clearly favor* [their] position, not simply that [they] are likely to succeed." *Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (emphasis in original).[5] A mandatory injunction "goes well beyond simply maintaining the status quo [p]endente lite [and] is particularly disfavored.'" *Id*. (citing *Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1320 (9th Cir. 1994)). "The "district court should deny such relief 'unless the facts and law clearly favor the moving party.'" *Id*. (citing *Stanley*, 13 F.3d at 1320). "In plain terms, mandatory injunctions should not issue in doubtful cases." *Id*. (citations omitted).

Here, MET is seeking a mandatory injunction by demanding that Hologenix make certain statements, post content on its social media accounts and send notices to its customers. Accordingly, the correct standard to analyze its entitlement to the injunction is not likelihood of success on the merits, but rather whether the "facts and law clearly favor" MET. They do not.

"Under the Lanham Act, a *prima facie* case requires a showing that (1) the defendant made a false statement either about the plaintiff's or its own product; (2) the statement was made in commercial advertisement or promotion; (3) the

[5] When the injunction requested requires the opposing party to take affirmative action, "the relief is treated as a mandatory injunction." *Garcia*, 786 F.3d at 740 (citing *Marlyn Neutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 879 (9th Cir. 2009)).

statement actually deceived or had the tendency to deceive a substantial segment of its audience; (4) the deception is material; (5) the defendant caused its false statement to enter interstate commerce; and (6) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to the defendant, or by a lessening of goodwill associated with the plaintiff's product." *Newcal Indus., Inc. v. Ikon Office Sol.*, 513 F.3d 1038, 1052 (9th Cir. 2008). Additionally, the U.S. Supreme Court determined that a plaintiff pursuing a Lanham Act claim must demonstrate that its injuries are proximately caused by violation of the Lanham Act. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 132-34, 134 S. Ct. 1377, 1390-91 (2014). Here, the facts and law do not "clearly favor" MET and it is not entitled to a mandatory injunction.

1. Hologenix's FDA-determined statements are not deceptive

MET argues that Celliant's "FDA-determined" advertising is false because the FDA has made no determinations regarding Celliant. [Motion at § III.B.] However, this assumption is false because FDA made a determination regarding Celliant and advised about the language that Hologenix could use in marketing the product. [*See* § II.B, *supra*.] FDA based its decision on an evaluation of scientific information within its area of technical expertise after FDA spent almost a decade interacting with Hologenix. [Casden Decl., ¶¶ 11-30; Billing Decl., at ¶¶ 21-24.] It is black-letter law that this decision must be afforded deference. *See United Food and Commercial Workers v. NLRB*, 307 F. 3d 760 (9th Cir. 2002) (citing *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*, 467 US 837, 104 S. Ct. 2778 (1984) (A court may not substitute its own construction of a statutory provision for a reasonable interpretation made by an agency.))

MET is attempting to substitute FDA's firsthand interaction, analysis and findings with that of its own FDA expert Alberto Gutierrez. While Mr. Gutierrez may have detailed knowledge of how FDA operates in general, MET admits that Mr. Gutierrez "has not reviewed the correspondence between the FDA and

Hologenix." Yet he concluded that "the FDA has not made a determination about the underlying benefits of Celliant." [*See* Motion at 7:18-23.] This is the epitome of speculation, which is absolutely no probative value. In sum, there is insufficient evidence to determine that the law and facts clearly favor a determination that Hologenix's FDA-determined statements are misleading.

2. MET Cannot Show Materiality

The materiality element under the Lanham Act requires MET to demonstrate that Hologenix's alleged falsities or misrepresentations were "likely to influence the purchasing decision" of customers of the product. *ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. App'x. 609, 613 (9th Cir. 2016); *see also Pestube Sys., Inc. v. HomeTeam Pest Def., LLC,* 2008 WL 11448028 at *7 (D. Ariz. 2008) (citing *Rice v. Fox Broadcasting* Co., 330 F.3d 1170, 1180 (9th Cir. 2008)). As detailed below, MET cannot meet this requisite element either.

In *Pestube,* for example, the plaintiff alleged that false statements by the defendant caused it to lose two contracts with homebuilders based on statements by the two homebuilders to the plaintiff about the purportedly false statements. *Id*. at *8. The court held that this type of evidence was insufficient because in order to establish materiality, the plaintiff was required to present evidence that the "false statements are likely to influence the homebuilders' purchasing decisions." *Id*. Here, the only evidence presented that Hologenix's allegedly false statements influenced either UA or ATC are the declaration of MET's President that ATC mentioned Hologenix's FDA status to him. This is the same type of evidence that was held insufficient in *Pestube*.

Without any factual support, MET was left to conduct a consumer survey, but that survey is meaningless as MET's expert surveyed the wrong population. An expert's opinion and survey evidence may be admissible to prove materiality in an action for false advertising where the survey demonstrates that competitor's allegedly false or misleading statements influenced ***consumers'*** purchasing

decisions. *See ThermoLife*, 648 Fed. App'x. at 613. However, a survey must rely on responses by potential customers of the products in question. *Kournikova v. Gen. Media Communications Inc.*, 278 F. Supp. 2d 1111, 1125 (C.D. Cal. 2003) (excluding survey that did not survey potential customers of the product).

Here, MET has pled that the actual purchasers of both Hologenix and MET's products ***are not consumers***, but rather sophisticated manufacturers, like UA and ATC. [*See* Complaint, Doc. 1 ¶¶ 13, 15; *see also* Motion, Doc 24, at 11.] MET did not survey these potential Hologenix customers.[6] [*See* Ex. A to Maronick Decl., Doc. 24-8.] This consumer survey is thus nonprobative of whether Hologenix's statements were likely to affect the purchasing behaviors of its *purchasing* customers (i.e. manufacturers such as UA or ATC). Further, the conclusion Dr. Maronick draws from the survey -- that a significant number of consumers believe that the FDA has determined that Celliant is a medical device and medical wellness product -- is unremarkable because his conclusion matches FDA's determination. [Maronick Decl. at ¶ 18.] Finally, many of Dr. Maronick's findings undermine MET's claim of false advertising. For example, as noted in Table 3 of his report, the largest percentage of consumers (39.2%) that were shown the "FDA determined" language believed that FDA had determined that Celliant was a medical wellness device, which is the truth. *See* Ex. A to Maronick Decl., Doc. 24-8 at pp. 8-9. Only 4.1% thought the "FDA determined" language meant "approved by the FDA." *Id*. at p. 9. All other responses were also at or under 10%. *Id*. As such, even if one were to rely on Dr. Maronick's survey, it shows that Hologenix accurately conveyed FDA's determination.

Moreover, MET has failed to produce **any** evidence that the purchasing decision by sophisticated manufacturers for contracts worth hundreds of millions of

[6] Dr. Maronick has not disclosed the profession of those surveyed. [*See* Ex. A to Maronick Decl., Doc. 24-8.] All he noted is that nearly half of those surveyed are between the ages of 25 and 44, and 72% are female. [*Id*. at p. 6.] There is no evidence that these demographics represent the decision-makers at manufacturers that purchase Celliant.

dollars would be influenced by a handful of social media posts or third party news articles. Indeed, it strains credulity that a sophisticated manufacturer such as UA would be more influenced (or influenced at all) by a Twitter hashtag as opposed to the many in-person meetings with Hologenix over nine years or the clinical trials that Hologenix sponsored to demonstrate Celliant's effects.

3. MET is Not Owed a Presumption of Materiality

MET argues that it is entitled to a presumption of materiality because the statements made by Hologenix were false or false by implication; however, the Ninth Circuit has not determined that such a presumption exists. *Pestube Sys.*, 2008 WL 11448028 at * 8 ("The Court has found no instance where a court in the Ninth Circuit held that the rebuttable presumption applies to the element of materiality in either comparative false advertising or non-comparative false advertising cases."); *see also Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 310 F. Supp. 3d 1089, 1125 (S.D. Cal. 2018) ("The Court is not convinced that the Ninth Circuit has likewise determined that materiality is presumed for actually false statements, nor has FRI cited to a Ninth Circuit case stating this.").

For support of its proposition that such a presumption exists, MET is forced to rely on a single case from the District Court of Oregon, which relied on a case from the Second Circuit. *See* Doc. 24 at 24 (citing to *FLIR Sys., Inc. v. Sierra Media, Inc.*, 903 F. Supp. 2d 1120, 1129 (D. Or. 2012) (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 157 (2d Cir. 2007)). Both of these cases are distinguishable from the case at hand because they concern comparative advertisements - that is, advertisements that directly or indirectly compare one product to another - and the sought after injunction only prevented the defendants from making infringing statements. *See FLIR*, 903 F. Supp. 2d at 1127; *see also Time Warner*, 497 F.3d at 152, 158.

Because this case does not involve comparative advertisements, the Court should not find that MET is entitled to a presumption of materiality where the Ninth

Circuit has not adopted the principle and instead requires that materiality be proven by actual effect of the statement at issue on the purchaser's decision.

4. MET Cannot Establish Proximate Causation

In order to be entitled to a preliminary injunction for a Lanham Act claim, a plaintiff must offer evidence that its damages were proximately caused by the plaintiff's purported violations of the Lanham Act. *See, e.g. Lecheek*, 2015 WL 12659907 at *7; *see also Snac Lite, LLC v. Nuts 'N More, LLC*, 2016 WL 6778268, at *13 (N.D. Ala. 2016); *Lundgren v. AmeriStar Credit Sols., Inc.*, 40 F. Supp. 3d 543, 551 (W.D. Pa. 2014). "To establish proximate cause under section 1125(a), a plaintiff 'ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff.'" *Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 165 F. Supp. 3d 937, 946 (S.D. Cal. 2016) (citing *Lexmark*, 572 U.S. 118, 134, 134 S. Ct. 1377, 1391)).

MET has not shown any evidence that an adverse purchasing decision was made by UA, ATC or any other manufacturer because of any of Hologenix's statements. MET has also failed to provide any admissible evidence regarding the *impact* the purportedly false or deceptive statements had on manufacturers and therefore are not likely to succeed on its claim under the Lanham Act.

In contrast, Hologenix has provided evidence in this response and corresponding declarations of other possible bases for UA's decision to award a contract to Hologenix. Specifically, Hologenix spent 10 years working with the FDA on Celliant, received a 513(g) letter and conducted numerous clinical studies specific to Celliant. [Casden Decl., ¶¶ 11-30.] UA might well have decided that the FDA determination regarding Celliant was beneficial, it might also have made the decision to switch based on eight years of working with Hologenix. UA also may have not had a productive relationship with MET or did not like the quality of MET's products. MET only had two clients during the course of its existence, so

there could be a myriad of factors related to UA's decision that have nothing to do with a few tweets from Hologenix. MET has failed to meet its burden that any purchasing decision was made due to the complained-of statements.

5. MET's Lanham Act Claim is Barred by its Unclean Hands.

"[T]he unclean hands doctrine provides a defense to false advertising claims under the Lanham Act." *Emco, Inc. v. Obst*, 2004 WL 1737355, at *4 (C.D. Cal. 2004) (citing *Japan Telecom, Inc. v. Japan Telecom Am., Inc.*, 287 F.3d 866, 870 (9th Cir. 2002)). As the Supreme Court noted over a century ago, "it is essential that the plaintiff should not in his trade mark, or in his advertisements or business, be himself guilty of any false or misleading representation...." *Worden v. California Fig Syrup Co.*, 187 U.S. 516, 528 (1903); *see also Levi Strauss & Co. v. Shilon*, 121 F.3d 1309, 1313 (9th Cir. 1997) (holding that to obtain Lanham Act injunction, "[e]quity requires that those seeking its protection shall have acted fairly and without fraud or deceit as to the controversy in issue.")

To prevail on an unclean hands defense, the defendant must demonstrate that the plaintiff's conduct is inequitable and that the conduct relates to the subject matter of its claims. *Fuddruckers, Inc. v. Doc's B.R. Others, Inc.*, 826 F.2d 837, 847 (9th Cir. 1987). Here, there are numerous examples of MET's false advertising. MET admits that it operates both the Redwave and Biopower websites, which are different brand names for its bioceramic material (the "MET Product"). [MET Answer to Hologenix Counterclaim, Doc. 19 at ¶¶ 9-15]. MET also admits that it has advertised and continues to advertise the benefits of the MET Product. [*Id*. at ¶ 29]. These claimed benefits include:

- "Products powered with BIOPOWER™ have the unique ability to help improve biological functions. BIOPOWER™ is designed to help the body restore itself and generate natural energy by increasing cellular metabolism, inducing analgesia, promoting muscle relaxation, and decreasing inflammation and oxidative stress."
- That the MET Product allows the body "to recover and heal quicker."

- "Well documented, tested and proven in numerous medical and scientific publications, far infrared has been shown to support an increase in cellular metabolism, fight inflammation, promote cell energy and reduce oxidative stress. Ultimately, by working with you, BIOPOWER™ helps promote recovery from life's daily activities, allowing the body to return to a healthy state."
- "By harnessing the physiological benefits of Far Infrared, we created therapeutic apparel able to improve health as it's worn – making recovering from an all-out effort faster, easier, and more efficient."
- "How one sleeps at night affects focus, performance, and overall functioning during the following day. Using Redwave's technology, this new line works to restore the body, assuring you'll rest easy and wake up refreshed."

[*Id*. at ¶¶ 31-32, 64, 68; *see also* Declaration of Noel Cohen, at ¶¶ 4-8].

MET admits that it did not obtain approval from the FDA to make these statements regarding the MET Product. [*Id*. at ¶ 38]. MET even admits that it has no evidence to support its claims that the MET Product supports "healing" or "prevention." [*Id*. at ¶ 60]. Notably, FDA told Hologenix that several of the above statements are not allowed, including the statements regarding cellular metabolism, decreasing inflammation and healing quicker. [Casden Decl., ¶ 24]. MET also admits that it has only six studies of the MET Product available its website, three of which are on rodents not humans. [MET Answer to Hologenix Counterclaim, Doc. 19 at ¶¶ 48, 51-56; Cohen Decl., at ¶ 9]. Yet, MET contends that it does not have sufficient knowledge to be able to say whether rodent studies are competent to substantiate the claims it makes relating to human performance or that the studies it has made available are only illustrative and cannot be used to support the MET Product's efficacy as opposed to IR research generally. [*Id*. at ¶¶ 56-59].

MET's own false advertising bars any injunctive relief because MET's conduct is inequitable and relates to the exact same subject matter over which they seek an injunction – claims regarding a bioceramic material.

D. <u>The Balance of Hardships Favors Hologenix</u>

To obtain a preliminary injunction, the moving party must demonstrate "that,

considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted," and that it is in the public's interest to issue the injunction. *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391, 126 S. Ct. 1837, 1839 (2006). Contrary to MET's assertions, an injunction here would not "merely level the playing field," but would instead be an impediment to legitimate competition.

MET's proposed injunction would require Hologenix to send statements to every manufacturer that has used Celliant, issue daily statements on its various social media platforms, issue statements on its website's landing page, and issue a press release stating that Hologenix's statements regarding "FDA approval" and "FDA determination" are false. Motion at pp. 22-23. Such an affirmative injunction would tip the balance of hardships sharply in favor of Hologenix because mandating Hologenix make these statements – **before a determination on the merits** – would result in a loss of reputation and goodwill, without due process. MET, on the other hand, has not met its burden of proof for a preliminary injunction. It has not established irreparable harm or that the facts and law strongly favor it. To the contrary, MET cannot show irreparable harm, materiality or proximate cause. Without such showing, it would be unconscionable to order Hologenix to make affirmative statements such as those requested by MET in its affirmative injunction.

E. <u>An Injunction is Not in the Public Interest</u>

MET argues that an injunction is in the public interest because enjoining Hologenix from making false representations would promote "public safety." *See* Motion at 21:14-15. However, none of the statements that MET is demanding that Hologenix make on its website, every day on social media or any other communication method, contain any warning about public safety. This case is simply not about consumer products that implicate the public's safety.

Courts will not grant a preliminary injunction "unless those public interests outweigh other public interests that cut in favor of not issuing the injunction." *All*

for the Wild Rockies v. Cottrell, 632 F.3d 1127, 1138 (9th Cir. 2011). "The public interest analysis for the issuance of a preliminary injunction requires [the court] to consider whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Id*. Here, the public interest factor favors denial of the Motion because it is now well-established that commercial speech is "entitled to substantial First Amendment protection." *Ohralik v. Ohio State Bar Association*, 436 U.S. 447, 455-56 (1978); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 637 (1985).

The U.S. Supreme Court requires that efforts to control the speech of commercial entities must meet the standard of "intermediate scrutiny." *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY*, 447 U.S. 557, 564-66 (1980). The Supreme Court explained that the appropriate test is: 1) whether the commercial speech concerns a lawful activity and is not misleading; 2) whether the government interest asserted to justify the regulation is "substantial"; 3) whether the regulation "directly advances" that government interest; and 4) whether the regulation is no more extensive than necessary to serve that interest. *Id.*

Hologenix recognizes that agencies and courts may prohibit the publication of "misleading" statements. But the remarkably overbroad and unprecedented relief requested by MET – a competitor of Hologenix – fails to satisfy the remaining three prongs. MET fails to recognize that it seeks not merely to admonish or remove the few erroneous statements made by Hologenix regarding FDA approval, but actually demand that this Court order Hologenix to *affirmatively* issue corrective advertising.

MET offers a single case in support of its request for corrective advertising – *Healthport Corp. v. Tanita Corp. of Amer.* Although the false advertising at issue in *Healthport* was determined at summary judgment to be literally false (including Healthport's CEO falsely stating he had technical degrees), the court found that corrective advertising was not necessary because there was "no evidence that a

large audience actually viewed the site or that consumers were and continue to be deceived." 563 F.Supp.2d 1169, 1182 (D. Or. 2008). The same should hold true here. There is literally no evidence that any of the alleged false statements were actually viewed by any customers or consumers of Hologenix or MET. Further, MET has offered no legal support for the notion that corrective advertising is necessary when the product is not sold directly to individual consumers, but rather only to manufacturers.

This underscores the constitutional infirmity of the requested relief, because "forced speech" may violate First Amendment principles, which are applicable to commercial enterprises, such as Hologenix. *See, i.e. U.S. v. United Foods, Inc.*, 533 U.S. 405, 410 (2001). By demanding "forced speech" in such a broad, burdensome and unprecedented manner, MET's requested relief fails the bulk of the *Central Hudson* test. MET has not cited any instance where the government interest was satisfied by forcing a company to go as far as to distribute lengthy and "curative" language, based on the limited evidence presented by MET.[7]

More fatal to the requested relief and the greatest constitutional infirmity at bar is that the requested relief is far from "narrowly tailored to achieve the governmental interest." Rather, it looks like a shopping list of every available form of communication, and the proposed language of the requested relief reads more like a *mea culpa* than it does simply supplying the relevant consumer base with information to avoid future harm. First Amendment jurisprudence regarding commercial speech was designed to balance the ***public interest*** with free speech rights: not the ***public relations*** wish list of a competitor that did not get a contract they wanted. Therefore, in light of the unconstitutional burden the proposed

[7] As mentioned *supra*, one of the critical evidentiary infirmities of the Motion is that it does not provide the Court with any data about how many readers received the errant tweets, social media posts or articles, and instead relies on an expert report based on a vague "what would you think?" question posed to random testers rather than the relevant consumer, a sophisticated manufacturer.

injunction would impose on Hologenix, an injunction is not in the public interest.

F. The Scope of the Injunction Sought is Extremely Overbroad

An injunction must be "tailored to eliminate only the specific harm alleged." *E. & J. Gallo Winery v. Gallo Cattle Co.*, 967 F.2d 1280, 1297 (9th Cir. 1992). Hologenix has conceded that there were a handful instances wherein it – or third-party journalists – erroneously referred to Celliant as "FDA approved." MET acknowledges in its application that Hologenix has removed these statements as soon as MET raised the issue. *See* Doc 24 at 9, 12. Hologenix has also taken steps to ensure that reference is not repeated, such as removing such references from its social media posts. [*See* Casden Decl at ¶ 38.] Simply put, there is nothing to enjoin here. *See, e.g. Lecheek Nutrition*, 2015 WL 12659907, at *7 (need for injunction is mooted where allegedly wrongful behavior has ceased).

Moreover, the requested injunction is punitive, harassing, overbroad and would compel Hologenix to make commercial speech, and possibly infringe on its First Amendment rights. MET is significantly overreaching as it attempts to destroy Hologenix's brand and goodwill. The injunction sought by MET is grossly over broad and this Court should deny it on those grounds.

IV. CONCLUSION

MET seeks a preliminary injunction solely based on (1) conclusory, unsupported hearsay statements by MET's CEO; (2) the declaration of a former FDA Director who admittedly knows nothing about the interactions between FDA and Hologenix; and (3) an irrelevant survey of the general public instead of the actual purchasing consumer--manufacturers and their purchasing managers. MET has not come close to meeting its heavy burden. The Motion should be denied.

Dated: May 10, 2019

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